

REMARKS

Reconsideration of the present application is respectfully requested. In the response to a Final Action Applicants amended claim 1, but the amendment was not entered as raising new issues that required further searching. Applicants filed an RCE incorporating the unentered amendments. In this RCE, these claims were again rejected in view of the same reference. In particular, claims 1 and 3-8 were said to be anticipated by Schlapfer, while claim 31 was said to be rendered obvious by this reference.

In tendering the anticipation rejection of independent claim 1, it was asserted that Schlapfer shows a compressible flexible element that is configured to expand along the longitudinal axis of the stabilization element, as well as an adjustment element configured to compress the flexible element to adjust its flexibility. The element 2e shown in FIG. 8 was said to satisfy these structural limitations. It is assumed that this element 2e was selected because it appears to be showing alignment with the longitudinal axis of the connecting element 3e. According to the Schlapfer specification, it further appears that the element 2e has the same construction as the clamping element 2 shown in FIGS. 1-2.

The element 2 was said to be compressible because when its collet construction is expanded it is pressed against the inner walls of the borehole 31 to lock the components together. The element was further said to expand along the longitudinal axis because its collet construction causes it to expand in all directions, which would necessarily include the direction of the axis. Finally, the nut 6 was regarded as configured to compress the element 2 and thereby adjust its flexibility. The expansion of the collet structure of the member 2 and the resulting "compression" against the inner walls of the borehole was considered to correspond to adjusting the flexibility of the element.

The rejection of claim 1 relies upon an incorrect definition of the terms "compressible" and "compress", namely being "pressed against something". This definition led to the conclusion that the Schlapfer element 2 is "compressible because it pressed against the inner walls of the borehole ref #31 to lock the components together." However, the verb "compress" means "to squeeze

together, constrict, contract, shrink" (Merriam Webster) or "to force into less space" (Webster's Unabridged Dictionary). The collet-type member 2 in Schlapfer moves in exactly the opposite manner – it expands in all directions as a result of the slits 24, as admitted in the Office Action. The entire function of the Schlapfer device relies upon the expansion of the member 2 into contact with the bore 31. The device cannot lock unless the member 2 is expanded.

It is well-known that collet-type devices rely upon frictional contact between the expanding surface and the contact surface. Tightening the collet increases the normal force between the two surfaces, which increases the friction force that must be overcome to permit relative movement. There is nothing in the Schlapfer reference that suggests that the collet member 2 operates in any manner other than to create a friction force between the member 2 and the surface 31. Tightening the nut 6 and conical head section 11 simply increases the normal force, which increases the friction force between the two surfaces. The primary object of the clamping element 2 in Schlapfer is to clamp, meaning that there is no movement between the screw 1 and the connecting piece 3. If the forces associated with tightening the nut 6 are absorbed by compressing the clamping element 2, then its clamping function is disrupted.

In short, there is nothing in Schlapfer that suggests that there is any compression of the collet member 2. More specifically, there is nothing in Schlapfer that suggests that the expanding collet member 2 in that reference is "squeezed" or "forced into less space". Instead, that member 2 is expanded into greater space.

Claim 1 further calls for the element to be "flexible". Although not expressly stated, the "flexibility" of the collet element 2 of Schlapfer is a result of the slits 24 and 27 that allow the collet segments to expand outwardly. It was suggested that the adjustment member 6 "appears" configured to compress the element and thereby adjust its flexibility. Nothing in Schlapfer was cited to support this conjecture as to what the adjustment member "appears" to do. In fact, there is nothing in Schlapfer to suggest that any part of the device is operable to adjust whatever flexibility is present in the collet member 2 or in any

other component of the device. There is certainly no evidence that expanding the collet member 2 in any way alters its flexibility. There is certainly no evidence that anything but the outer diameter of the collet member 2 can be adjusted. There is certainly no engineering justification for the conclusion that expanding the collet member 2 into the borehole and the "resulting compression against the inner walls of the borehole" can be considered to adjust the flexibility of the collet member 2, which is what is required by the claim. Simply restricting the outward expansion of the collet does not "adjust the flexibility". There is simply no evidence that locking the collet member 2 in any way alters its flexibility.

Notwithstanding these errors, Applicant has amended claim 1 to further clarify the adjustment feature of the invention. As disclosed in this application, the compressible flexible element is operable to permit some movement of the bone anchor relative to the stabilization element even after the construct has been fully tightened. This is in contrast to the device in Schlapfer in which the components are intended to be immovably locked together, as recognized in the Office Action, (e.g., "the element becomes tightly locked in the borehole ...", O.A. p. 6).

The Schlapfer reference is silent as to the material of any of the components of the fixation system and locking mechanism. However, at col. 3, lines 53-56, reference is made to "a suitable pairing of materials between the clamping piece [element 2] and the fixation piece [screw 1], [so] friction between the two components is kept to a minimum." This language at least suggests that the element 2 is not formed of an elastomeric material, such as silicone or rubber, because the resulting friction would frustrate smooth low-friction movement of the conical head section 11 of the bone fastener within the tapered borehole 21 of the locking element 2. At a minimum, it cannot be said that Schlapfer discloses or contemplates the locking element 2 being flexible to permit relative pivoting of the bone screw after the assembly is locked together.

Applicants have amended claim 1 to clarify that the adjustment element is configured to adjust the flexibility of the compressible element to adjust the amount of relative pivoting permitted between the bone anchor and the

stabilization element. As explained in the present specification, as the compressible element is further compressed, its flexibility decreases, which thereby reduces the amount of relative pivoting permitted between the bone anchor and the stabilization element. No such characteristic is described or even remotely contemplated in the Schlapfer reference. Again, Schlapfer is concerned with locking the entire construct together. Since there is no discussion of relative pivoting, or "micro-motion" in Schlapfer, there is certainly no discussion of adjusting the amount of that pivoting.

It is thus believed that the Schlapfer reference is insufficient to anticipate or render obvious Applicants' claim 1, either as originally presented or as amended herein. Thus, claim 1 and all of its dependent claims are believed to be patentable over the art of record.

It is further noted that certain of the dependent claims recite features that are not found in the cited art. For instance, dependent claim 4 recites that the bearing element is received within a bearing race and that the adjustment element is arranged to compress the bearing element within that race. In the Office Action, FIG. 8 of Schlapfer is excerpted with arrows pointing to different structure said to correspond to Applicants' claim elements. An indicator for "bearing race" appears to be pointing to the end of the connecting element 3e that forms the spherical borehole 31, rather than a separate bearing race disposed within that borehole. The Schlapfer does not disclose a bearing race, as that term is understood in the art and used in the present application, so it cannot anticipate claim 4.

Claim 6 defines the adjustment element as including a nut that is "arranged to compress said flexible element as said nut is threaded onto said threaded portion." Although not specifically identified in the Office Action it is presumed that the sentence at p. 3, lines 11-15, is intended to refer to this limitation, which states that the "flexible element is compressed between the intermediate portion and the nut when the nut is threaded onto the threaded portion." However, a review of FIG. 1 shows that this presumed action of the nut and intermediate portion does not occur. As the nut 6 is tightened, it pulls the

intermediate portion 11 upward into the conical borehole 21 of the clamping element 2. As this occurs, the collet-type clamping element expands outward, as it must to effect locking the assembly. It should be clear that the expanding portions of the clamping element 2 must slide relative to the nut 6. In the Office Action, it is repeatedly stated that this outward expansion results in "compression" of the element 2. Under this interpretation, it is the intermediate portion 11 that "compresses" the element 2, not the nut 6, as required by Applicants' claim 6. In other words, Schlapfer does not disclose the nut 6 being arranged to compress the flexible element as it is tightened, so this reference cannot be said to anticipate claim 6.

Claim 7 depends from claim 6, so the same arguments apply to traverse the anticipation rejection of this claim. Moreover, claim 7 further recites that the flexible element is compressed between the nut and intermediate portion. According to the Office Action, the element 2 is "compressed" between the intermediate portion and the spherical borehole, not between the nut and the intermediate portion. Again, as discussed above, the expanding portions of the element 2 must slide relative to the nut 6 in order for the Schlapfer locking mechanism to work.

Applicants have introduced a new claim 32 which depends from allowable claim 1. This claim further defines the manner in which the flexible element is compressed. More specifically, claim 32 defines this compression to occur along an axis that is substantially parallel to the longitudinal axis of the stabilization element. Even if the definition of "compression" set forth in the Office Action is accepted, that "compression" occurs along the longitudinal axis of the connector due to the outward expansion of the locking element 2. There is no disclosure or suggestion of compressing the locking element 2 in a direction perpendicular to the line of action between the locking element 2 and the spherical borehole 31. Thus, claim 32 is believed to be patentable over the art of record.

In view of the foregoing discussion and clarification of the Schlapfer disclosure, Applicants' request that the rejections of claims 1-8 and 31 be withdrawn. It is believed that pending claims 1-8 and 31, and new claim 32, are

novel and non-obvious over the Schlapfer reference. The Examiner is invited to contact the undersigned agent of record if it is believed that a telephonic interview may help place this application in condition for allowance.

Respectfully submitted,

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